

# Overview of gene technology regulation in Australia

In Australia, all activities with a GMO need legal authorisation. A set of laws[1](#_bookmark0) control what people can do with gene technology and genetically modified organisms (GMOs). The Gene Technology Regulator (the Regulator) administers these laws with the help of the staff in the Office of the Gene Technology Regulator (OGTR).

For example, if a GMO is grown in a field, or used in a clinical trial it will require a licence from the Regulator. Some GMOs used in a laboratory may also require a licence

These laws are designed to protect people and the environment by identifying risks from gene technology and managing those risks.

In order to assess the risks from the GMO the Regulator requires information about the GMO and the proposed work. While the applicant may want to keep some of this information secret, they must tell the Regulator so the right licence decision can be made.

**What is Confidential Commercial Information (CCI)?**

Confidential Commercial Information (CCI) is information belonging to a person or organisation which they want to keep secret.

1 The Commonwealth *Gene Technology Act 2000,* the Gene Technology Regulations 2001 and corresponding state laws.

# What information can be declared as CCI?

The gene technology laws require the Regulator to be transparent in decisions regarding this technology. However, the same laws also allow information to be declared as CCI by the Regulator.

# What information is not usually declared as CCI?

The Regulator may refuse to declare information as CCI when the public interest in releasing the information outweighs any likely loss to the person or organisation requesting the CCI declaration.

**Why might CCI be needed?**

A company which has a commercial advantage over competitors because they are using a novel gene sequence in their GMO could lose that advantage if the information were widely known. The company could ask for this type of information to be treated as CCI.

The locations where GM plant field trials are grown cannot be declared as CCI, except under particular circumstances where significant damage to people, environment or property would be likely to occur.

# Who can see CCI?

The Regulator and OGTR staff must not reveal CCI, except to make it available to the scientific experts and government agencies that are consulted by the OGTR during the decision making process.

**Information can be declared CCI if:**

* It is a trade secret; or
* it has a commercial or other value that may be compromised if the information were disclosed; or
* it concerns lawful commercial or financial affairs that could be unreasonably affected if the information were disclosed.

**Further reading**

Genetically modified organisms in Australia

How are genetically modified organisms (GMOs) regulated in Australia?

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| Version 1 | August 2018 |

*This fact sheet contains general information intended for members of the public. Organisations or applicants wishing to apply for a CCI declaration should seek their own legal advice.*

